Sovereign Pharmaceuticals, Ltd.

Division of Dockets Management
HFA – 305
Food and Drug Administration
5630 Fischer Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

I am the President of Sovereign Pharmaceuticals Ltd., a pharmaceutical company located in Fort Worth, Texas. We employ a workforce of 100 people. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Fed. Reg. 60,702) Docket number 2003D-0478.

The pharmaceutical products that my company manufactures have a long history of safe and effective use. They are prescribed by supervising physicians and are routinely covered by medical insurance. It is important that FDA implement a regulatory scheme that does not reduce the availability or affordability of these important products. For this reason, I believe a prescription drug monograph (PDM), similar in structure to the current over-the-counter monograph system, should be a component of FDA's draft guidance.

A PDM would increase the regulatory scrutiny of prescription drug products that are currently being marketed outside the FDA pre-market approval system. It also would lower the drug costs for consumers by avoiding the short-term regulatory monopolies that can result under the current regulatory structure. Finally, it would be a more efficient use of FDA resources since a single monograph would obviate the need for FDA review of potentially thousands of similar pre-market approval applications.

For these reasons, I urge the Food and Drug Administration (FDA) to issue a revised solicitation for comments on its draft guidance. The revised solicitation should broaden the proposed Compliance Policy Guide (CPG) to consider a PDM system that Congress has directed FDA to consider. By doing this, the public comments will assist FDA in assessing the relative merits of its currently proposed guidance with a broader approach that includes a PDM allowing certain prescription drugs to be marketed without FDA pre-market approvals.

Thank you for the opportunity to submit comments on this important matter.

Sincerely,

Larry Boos, Ph.D.
President & CEO
Sovereign Pharmaceuticals, Ltd.

03D-0478 C56

MARNEL

MARNEL PHARMACEUTICAL, INC.

206 Luke Street • Lafayette, La. 70506
337/232-1396 • FAX 337/232-1491

December 17, 2003

Division of Dockets Management
HF-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

I am the President of MARNEL PHARMACEUTICAL, INC. , a pharmaceutical company located in Lafayette, Louisiana. We employ a workforce of seven and have and addition sales force of two in Louisiana and soon to be more in the country. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Red. Reg. 60,72) Docket number 2003D-0478.

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Thank you for the opportunity to submit comments on th is important matter.

Sincerely,

James A. Kreamer, Sr.
President

/jmt

MARNEL

MARNEL PHARMACEUTICAL, INC.

206 Luke Street • Lafayette, La. 70506
337/232-1396 • FAX 337/232-1491

December 17, 2003

Division of Dockets Management
HF-305
Food and Drug Administration
5630 Fishers Lane
Room 1061
Rockville, MD 20852

I am the Chairman of MARNEL PHARMACEUTICAL, INC. , a pharmaceutical company located in Lafayette, Louisiana. We employ a workforce of seven and have and addition sales force of two in Louisiana and soon to be more in the country. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Red. Reg. 60,72) Docket number 2003D-0478.

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Thank you for the opportunity to submit comments on th is important matter.

Sincerely,

Bernard C. Thibeaux
Chairman

/jmt

CAPELLON
PHARMACEUTICALS, LTD

Division of Dockets Management
HFA – 305
Food and Drug Administration
5630 Fischer Lane
Room 1061
Rockville, MD 20852

Dear Sir or Madam:

I am the Chairman of the Board of Capellon Pharmaceuticals Ltd., a pharmaceutical company located in Fort Worth, Texas. We employ a sales force of 35 people around the country. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Fed. Reg. 60,702) Docket number 2003D-0478.

The pharmaceutical products that my company manufactures have a long history of safe and effective use. They are prescribed by supervising physicians and are routinely covered by medical insurance. It is important that FDA implement a regulatory scheme that does not reduce the availability or affordability of these important products. For this reason, I believe a prescription drug monograph (PDM), similar in structure to the current over-the-counter monograph system, should be a component of FDA's draft guidance.

A PDM would increase the regulatory scrutiny of prescription drug products that are currently being marketed outside the FDA pre-market approval system. It also would lower the drug costs for consumers by avoiding the short-term regulatory monopolies that can result under the current regulatory structure. Finally, it would be a more efficient use of FDA resources since a single monograph would obviate the need for FDA review of potentially thousands of similar pre-market approval applications.

For these reasons, I urge the Food and Drug Administration (FDA) to issue a revised solicitation for comments on its draft guidance. The revised solicitation should broaden the proposed Compliance Policy Guide (CPG) to consider a PDM system that Congress has directed FDA to consider. By doing this, the public comments will assist FDA in assessing the relative merits of its currently proposed guidance with a broader approach that includes a PDM allowing certain prescription drugs to be marketed without FDA pre-market approvals.

Thank you for the opportunity to submit comments on this important matter.

Sincerely,

Ralph Brown
Chairman of the Board
Capellon Pharmaceuticals, Ltd.

7509 FLAGSTONE STREET ★ FORT WORTH, TEXAS 76118 ★ PHONE (817) 595.5820 ★ FAX (817) 595.5935

December 22, 2003

Division of Dockets Management, HFA-305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville MD 20852

JOSEPH N. ALLEGRETTI, R. Ph.
PRESIDENT
AND CHIEF OPERATING OFFICER

Dear Sir or Madam:

I am President and COO of Laser Inc., a pharmaceutical company located in Crown Point, Indiana. We employ 23 people, including 13 sales persons. Our products are distributed in 37 and we have been in business for over 47 years. This letter is submitted as a comment on the "draft Guidance on Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003.(68 fed. Reg.60,702) Docket number 2003D-0478.

The pharmaceutical products, that our company distributes, have a long history of safe and effective use. They are prescribed by supervising physicians and are routinely covered by medical insurance, including Medicaid departments in many states. It is important that the FDA implement a regulatory scheme that does not reduce the availability or affordability if these important products. I believe if a prescription drug monograph (PDM), similar to the current over-the-counter monograph system, were a part of the FDA's draft guidance, it would help insure the availability of these products at reasonable prices.

A PDM would increase the regulatory scrutiny of prescription drug products that are being currently marketed outside the FDA premarket approval system. It would lower the drug costs for consumers by avoiding the short-term regulatory monopolies that can result under the current structure. This structure can also have negative economic effects on many companies like ours, and our employees. Another factor to consider would be the economic effect on state Medicaid programs, which receive rebates when these products are prescribed. Finally, it would be a more efficient use of FDA resources since a single monograph would obviate the need for FDA review of potentially thousands of similar premarket approval applications.

For these reasons, I urge the Food and Drug Administration to issue a revised solicitation for comments on its draft policy. The revised solicitation should broaden the proposed Compliance Policy Guide (CPG) to consider a PDM system that Congress has directed the FDA to consider. By doing this, public comment will assist the FDA in assessing the relative merits of its currently proposed guidance with a broader approach that includes a PDM allowing certain prescription drugs to continue to be marketed without FDA premarket approvals.

Thank you for the opportunity to submit comments on this important matter.

Sincerely,

Joseph N. Allegretti, R.Ph.
President & C.O.O.

LASER INC. 2200 W. 97TH PL. P.O. BOX 905 CROWN POINT IN. 46307 219 | 663-1165

Elge, Inc.
P.O. Box 944
Richmond, Texas 77406-0944
(281) 232-0463 Fax (281) 232-0476

December 17, 2003

Division of Dockets Management
HFA – 305
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear Sir or Madame:

I am President of Elge, Inc., a pharmaceutical manufacturer. Elge employs a workforce of 75 in the small town of Rosenberg, TX. This letter is submitted as a comment on the "Draft Guidance On Marketed Unapproved Drugs" that appeared in the Federal Register on October 23, 2003. (68 Fed. Reg. 60,702, Docket Number 2003D-0478).

The pharmaceutical products that my company manufactures have a long history of safe and effective use. They are prescribed by supervising physicians and are routinely covered by medical insurance. It is important that FDA implement a regulatory scheme that does not reduce the availability or affordability of these important products. For this reason, I believe a prescription drug monograph (PDM), similar in structure to the current over-the-counter monograph system, should be a component of the FDA's draft guidance.

A PDM would increase the regulatory scrutiny of prescription drug products that are currently being marketed outside the FDA premarket approval system. It also would lower the drug costs for consumers by avoiding the short-term regulatory monopolies that can result under the proposed regulatory structure. Finally, it would be a more efficient use of FDA resources since a single monograph would obviate the need for FDA review of potentially thousands of similar premarket approval applications.

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Thank you for the opportunity to submit comments on this important matter.

Sincerely,

Larry Gremminger, RPh
President